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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
|-----------------|-------------|----------------------|---------------------|------------------|

10/519,174

09/01/2005

Ralf Herwig

13027.60USWO

5243

23552 7590 05/16/2008

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EXAMINER

NATARAJAN, MEERA

ART UNIT

PAPER NUMBER

1643

MAIL DATE

DELIVERY MODE

05/16/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/519,174 | Applicant(s) HERWIG, RALF | |
| | Examiner MEERA NATARAJAN | Art Unit 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendments in the reply filed on 02/15/2008 is acknowledged and entered into the record.
2. Claims 1-6 are pending and will be examined on the merits.

Claim Rejections Maintained - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The rejection of Claim 1 under 35 USC 112 second paragraph as being indefinite is maintained. The language in Claim 1 is still confusing and difficult to decipher. The examiner would like to suggest amending the Claim to recite the active steps in outline form as shown below.

- a. A method for determining characteristics and/or classification of circulating macrophages and/or peripheral mononuclear blood cells comprising the steps of:
 - i. taking whole blood and performing gradient centrifugation to isolate macrophages
 - ii. performing perforation of said macrophage cells
 - iii. performing intracellular staining of said cells with at least one selected antibody; and
 - iv. performing flow cytometric analysis of said cells comprising subsequent counting and analysis of physical and molecular characteristics of a plurality of cells.

5. These amendments are merely a suggestion but would help clear up the indefinite nature of the claim. For example in line 6 of Claim 1 it recites “perforation and said macrophage cells”, does Applicant mean “of said macrophage cells”?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Rejection of Claims 1-6 under 35 USC 102 as being anticipated by Brandt et al. is maintained for the reasons of record. Applicants argue Brandt et al. does not perform the method claimed of isolating macrophages from a whole blood sample. Applicant's state Brandt et al. perform two separate methods of isolation which cannot be combined with one another and there is no evidence of significant cell numbers in the range of macrophages and/or monocytes to be found and the method taught by Brandt et al. is clearly directed to different identification. In addition Applicant's point out that in Figure 1C of Brandt et al. , the monocytes of the method performed are negative for PSA. Applicant asserts that the methods of Brandt did not lead to the results of the present application which provides a method for particular preparation and isolation of a certain cell group. Applicant's arguments have been carefully considered but not found persuasive.

8. The arguments presented above are directed more towards the results of the preparation method and not at the particular active steps recited in the claims. Brandt et al. clearly perform the active steps claimed and therefore would inherently read on a method of determining characteristics and/or classification of circulating macrophages and/or peripheral mononuclear blood cells. Applicant argues Brandt et al. teach two separate methods and the staining of gradient centrifuged cells is performed in the second method disclosed where the antibodies are added simultaneously and do not include perforation steps. This is incorrect. Brandt et al. clearly describe a method of "density gradient and immunomagnetical separation of blood-borne prostate-derived cells and cell clusters from freshly obtained peripheral blood of patients" (see p. 4556, right column). After which on p. 4557, right column (3rd full paragraph) they disclose by stating "the described isolation procedure (referring to the method recited on p. 4557) was applied to 40 ml of peripheral blood from 14 patients...The same cell was labeled with an anti-PSA antibody conjugated with FITC". Therefore, the active steps of the claims were performed by Brandt et al. and are independent on whether the macrophages/monocytes isolated were positively stained for PSA. The rejection under 35 USC 102 is maintained for the reasons of record.

All other rejections are withdrawn in view of the applicant's amendments and arguments set forth in the reply filed 02/15/2008.

Conclusion

9. Claims 1-6 are rejected.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEERA NATARAJAN whose telephone number is (571)270-3058. The examiner can normally be reached on Monday-Thursday, 9:30AM-7:00PM, ALT. Friday. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MN

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643